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IN THE UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

EDWARD FINCK, a single man, Plaintiff, v. PFIZER, INC., a Delaware corporation with its principal place of business in New York; PHARMACIA CORPORATION, a Delaware corporation with its principal place of business in New Jersey; MONSANTO CO., a subsidiary of PHARMACIA and a Delaware corporation with its principal place of business in Missouri; G.D. SEARLE & COMPANY, a Delaware corporation with its principal place of business in Illinois; Defendant.	**NO.** **COMPLAINT** **(TORT NON MOTOR VEHICLE; PRODUCT LIABILITY; NEGLIGENCE)** (Jury Trial Requested)

COMES NOW the Plaintiff, by and through undersigned counsel and alleges as follows:

INTRODUCTION

This case involves the prescription drug Celebrex®, which was manufactured, sold, distributed and promoted by defendants primarily as a pain reliever. Defendants misrepresented that Celebrex® was a safe and effective treatment for osteoarthritis and management of acute pain in adults, when in fact the drug caused serious medical problems. The safety of Celebrex® was publicly questioned on December 17, 2004 when The National Institutes of Health (NIH) announced that it had suspended the use of Celebrex® for all participants in a large colorectal cancer prevention clinical trial conducted by the National Cancer Institute (NCI).

JURISDICTION AND VENUE

1. At all times material hereto, Edward Finck was a resident of the State of Arizona.

2. Defendants Pfizer Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia"), Monsanto Co. ("Monsanto") and G.D. Searle & Co. ("Searle") tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold and distributed, or otherwise placed in the stream of interstate commerce, Celebrex®, which was ingested by the Plaintiff Edward Finck.

3. Defendant Pharmacia is a Delaware corporation with its principal place of business in New Jersey. On information and belief, said entity does business in the

state of Arizona, and at all times relevant herein, it developed, manufactured, marketed, distributed, and sold Celebrex® in interstate commerce.

4. Defendant Monsanto, a subsidiary of Pharmacia, is a Delaware corporation with its principal place of business in Missouri. On information and belief, said entity does business in the state of Arizona and at all times relevant herein, it developed, manufactured, marketed, and sold Celebrex® in interstate commerce.

5. Defendant Pfizer is a Delaware corporation with its principal place of business in New York. In 2003, Pfizer acquired Pharmacia for nearly $60 billion because of Celebrex®. During the relevant time period, Pfizer has been engaged in the business of marketing and selling Celebrex® nationwide and in Arizona.

6. Defendant Searle is a Delaware corporation with its principal place of business in Illinois. At all relevant times, Searle has been engaged in the business of marketing and selling Celebrex® nationwide and in Arizona.

7. The jurisdiction of this Court over the subject matter of this action is predicated on diversity of citizenship, 28 U.S.C. Section 1332. The amount in controversy exceeds $75,000.00, exclusive of interest and costs. Venue in this Court is proper pursuant to 28 U.S.C. Section 1391 in that a substantial part of the events or omissions giving rise to the claims asserted herein occurred in this District, and Defendants are subject to personal jurisdiction in this District.

GENERAL ALLEGATIONS

8. This is an action for personal injuries and damages brought on behalf of the Plaintiff. Plaintiff Edward Finck was prescribed and supplied with, received, and who had taken and ingested and consumed the prescription drug Celebrex®, as

tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, among other relief, general and special damages and equitable relief in order to enable the Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug and punitive damages for Defendants' conscious disregard for Plaintiff Edward Finck's safety.

9. The injuries and damages of Plaintiff were caused by the wrongful acts, omissions, and fraudulent misrepresentations of Defendants.

10. At all times herein mentioned, the Defendants were engaged in the business of, or were successor in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug known as Celebrex® for the use and ingestion by the Plaintiff Edward Finck.

11. At all times herein mentioned, the Defendants were authorized to do business in Arizona.

12. At all times herein mentioned, the officers and directors of the Defendants named herein participated in, authorized and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of

said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

13. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drugs were the cause of any appreciable harm sustained by him. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of his injuries at an earlier time because the injuries were caused without perceptible trauma or harm, and when the Plaintiff Edward Finck's injuries were discovered their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that he had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable statute of limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continued to misrepresent to the public and to the medical profession that the drugs are safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

14. Plaintiff Edward Finck took Celebrex® as prescribed by his physician and suffered a myocardial infarction on January 18, 2002 as a result.

FACTUAL ALLEGATIONS

A. Development of Celebrex®

15. Celebrex® is one of the new entries in a class of pain medications called nonsteroidal anti-inflammatory drugs ("NSAIDs"). Aspirin and ibuprofen are examples of well known NSAIDs.

16. NSAIDs reduce pain by blocking the body's production of pain transmission enzymes called cyclooxygenase or "COX." There are two forms of COX enzymes, COX-1and COX-2.

17. In addition to transmitting pain sensations, COX-1 is involved in maintaining and repairing gastrointestinal tissue.

18. In addition to transmitting pain sensations, COX-2 is involved in the production of prostacyclin, a substance responsible for preventing the formation of blood clots.

19. It is generally accepted in the medical community that blocking the COX-1 enzyme hampers the body's ability to repair gastric tissue and causes harmful gastrointestinal side-effects, including stomach ulceration and bleeding.

20. It is generally accepted in the medical community that blocking the COX-2 enzyme encourages the formation of blood clots and causes various clot-related cardiovascular events, including: heart attack, stroke, unstable angina, cardiac clotting and hypertension.

21. Traditional NSAIDs, like aspirin, reduce pain sensations by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional NSAIDs cause ulcers in the stomach and intestines. However, because of a complex chemical balance in the human body, traditional NSAIDs do not cause blood clots, but actually reduce the risk of clots and help to protect heart function.

22. For decades, in the absence of other treatment options, consumers seeking pain relief were forced to accept and live with the gastrointestinal risks of traditional NSAIDs.

23. Defendants set out to remedy this problem by developing "selective" inhibitors that would block only COX-2 production, thus (supposedly) allowing the proper maintenance of gastric tissue while still reducing pain sensations. In making this decision, Defendants either intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostacyclin levels, causes blood clots and gives rise to various clot-related cardiovascular events, including: heart attack, stroke, unstable angina, cardiac clotting and hypertension.

24. Pharmacia and Monsanto completed Phase I, II and III trials for their selective COX-2 inhibitor, Celebrex®, by 1998. During these trials, they learned that selectively inhibiting the COX-2 enzyme lowers prostacyclin levels, causes blood clots and gives rise to various clot-related cardiovascular events, including: heart attack, stroke, unstable angina, cardiac clotting and hypertension.

B. The CLASS Study

25. Thus, Defendants knew by 1998 that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors.

26. Despite knowing that Celebrex® posed serious cardiovascular risks for anyone who took them, Defendants made a business decision to push Celebrex® to market on claimed improvements in gastrointestinal safety while downplaying their cardiovascular dangers.

27. In order to justify this position, Defendants funded a significant clinical trial to demonstrate that Celebrex® had greater gastrointestinal safety than traditional NSAIDs: the Celecoxib Long-Term Arthritis Safety Study ("CLASS").

28. The CLASS trial, paid for by Pfizer, Pharmacia, Monsanto and Searle, was a long-term, double-blind study of gastrointestinal toxicity in 8,059 patients taking Celebrex®, ibuprofen or diclofenac to treat arthritis. Patients with heart problems were allowed to participate in the CLASS trial, and were permitted to take low doses of aspirin to reduce the risk that they would suffer an adverse cardiovascular event during the study.

29. Despite the fact that the CLASS studies secretly acknowledged the likelihood of cardiovascular events (as shown by the attention paid to whether participants would be permitted to take aspirin, a known cardio-protector, and the fact that the studies were both set up to record cardiovascular event data), Defendants intentionally diverted attention from cardiovascular risks of Celebrex® by providing the bare minimum of information on this issue: the CLASS trial did not publish any cardiovascular event data.

30. When the CLASS study was completed, the results were reported to the U.S. Food and Drug Administration's Arthritis Drugs Advisory Committee ("the Committee") as part of a request to exempt Celebrex® from including a gastrointestinal safety warning in its package insert.

31. After reviewing the CLASS results, the Committee concluded that patients taking Celebrex® had not experienced fewer gastrointestinal complications than those taking traditional NSAIDs. Without any proof of enhanced safety, the Committee recommended that the Celebrex® package insert contain the same gastrointestinal warnings as traditional NSAIDs, and advised further studies to assess the risk of COX-2 inhibitors when taken with aspirin.

32. Since the CLASS study did not report any cardiovascular event data and the Celebrex® Defendants were not seeking an exemption from any cardiovascular warning requirement (because traditional NSAIDs do not cause cardiovascular problems), the Committee did not consider the cardiovascular safety of Celebrex®.

33. Defendants' clinical studies did not have their intended effect: neither drug was permitted to claim increased gastrointestinal safety over traditional NSAIDs.

34. Defendants initiated extensive pre-release marketing campaigns to convey the uniform message that Celebrex® provided effective pain relief without the gastrointestinal side-effects of traditional NSAIDs. Defendants intentionally omitted any mention of cardiovascular risks from their marketing and advertising statements to benefit from the inference that Celebrex®, as a pain reliever in the NSAID family, had a cardio-protective effect.

35. Defendants also pushed ahead with their efforts to win approval from the U.S. Food and Drug Administration ("FDA") to sell Celebrex® in the United States.

36. Without having performed any significant tests on cardiovascular safety, the Celebrex® Defendants filed a new drug approval application with the FDA in August 1998. After an expedited review that addressed the CLASS gastrointestinal safety results but did not touch on any cardiovascular safety issues, the FDA approved Celebrex® for the relief of osteoarthritis and adult rheumatoid arthritis in December 1998. Celebrex® was released for sale in the United States in February 1999.

37. By this time, Defendants' intensive marketing campaigns were already showing positive results. Sales projections for both Celebrex® based on early orders and inquiries surpassed $2 billion per year.

38. Relying on these projections, Defendants made a "business decision" that their profits from the sale of Celebrex® could easily finance the defense or settlement of any litigation related to Celebrex®.

39. The results of the CLASS study were published in the September 13, 2000, issue of JAMA. CLASS is what's known as a Phase 4 post approval study, which was required by the FDA. Before any drug is approved, manufacturers have to submit data to the FDA that demonstrate the drug's safety and effectiveness.

40. CLASS, which included over 8000 people with rheumatoid and osteoarthritis, compared the risk of gastrointestinal problems in people taking Celebrex® with the risk in those taking ibuprofen (Motrin, Advil) and diclofenac (Voltaren). ***The article in JAMA concluded that Celebrex®, "when used for 6 months ... is associated with a lower incidence of clinical upper GI events than comparator NSAIDs (ibuprofen and diclofenac)."*** The accompanying editorial supported this conclusion: "The results of this important study ... provide ***promising data*** to suggest that [Celebrex® is] ... ***effective in reducing***, but not eliminating, the risk of symptomatic [minor] ulcers and [major] ulcer complications in the enormous number of individuals who might benefit from these drugs..."

41. There was, however, one very large problem. The manufacturer's original research plan, as submitted to the FDA, had defined the duration of the CLASS study that compared Celebrex® with ibuprofen as 12 months, and that of the study comparing Celebrex® with diclofenac as 16 months. And, indeed, the combined study had run for a full 12 months. ***The authors, however, submitted only the first 6 months for the article in JAMA.*** Left unreported (and unmentioned) in the JAMA

article were the data from the *second* 6 months of the study, during which time, as shown in the data on the FDA's website, ***six of the seven serious gastrointestinal complications that occurred were in patients taking Celebrex®***.

42. Pharmacia, the manufacturer of Celebrex®, presented a statistical argument to the FDA justifying its omission of the data from the second half of its study. The company claimed that since a higher percentage of people taking diclofenac dropped out of the study because of minor symptoms like heartburn, the data from the second half of the study were invalid because of what is called "informed censoring." The manufacturer argued that these dropouts would have gone on to develop serious gastrointestinal complications, and their dropping out of the study artificially minimized the risk of serious complications from taking diclofenac. The FDA flatly rejected this argument. It countered that there was no proof that the people with heartburn would have developed more serious gastrointestinal problems. Further, if minor symptoms caused people in the study to stop taking diclofenac, people in the real world would similarly stop taking the drug if it caused heartburn and would similarly protect themselves from going on to develop serious gastrointestinal complications.

43. The FDA's opinion of the manufacturer's decision to publish only half of the data from its study was clear: "the sponsor's presentations of 6-month data ... are not statistically valid or supportable." The FDA's gastroenterology reviewer concluded that the first 6 months of data – which had been presented in the JAMA article as if they were a report of the entire study – were not worthy of separate consideration: "Based on the lack of adequate rationale, these post-hoc analyses will not be further

discussed or presented in this review." Looking at the data from the entire year of the study, the FDA's gastroenterology reviewer concluded that "the sponsor has failed to demonstrate a statistically significant lower rate" of serious GI complications in the people who took Celebrex® compared with the people who took the other NSAIDs. When the reviewer looked at only the second six months of data (*i.e.*, the data that had not been published in the JAMA article), he concluded that the risk of serious GI complications appeared to be higher in the people who took Celebrex® "compared to both ibuprofen and diclofenac" (FDA's underscore). This was hardly an endorsement for a drug whose only advantage (besides the convenience of a once daily dosing) was that it caused fewer serious GI problems.

44. The disparity between the CLASS article published in JAMA and the information in the FDA's files by no means stopped there. The primary question that the CLASS study had been designed to answer had been changed, producing results that were far more favorable to the manufacturer. The original research design submitted to the FDA by the manufacturer of Celebrex® had stated: "The primary objective of this study is to compare the incidence of ***clinically significant*** [major] upper gastrointestinal events … in patients taking Celebrex® to patients taking NSAIDs." The term "***clinically significant***" refers to complications that would generally require hospitalization: active bleeding, perforation of the stomach or duodenum requiring surgery, or obstruction of the outlet of the stomach. The research plan specifically called for the less serious gastrointestinal side effects to "be categorized and analyzed separately." Indeed the FDA's gastroenterology reviewer specifically

commented that the plan to identify the "truly significant" serious gastrointestinal complications alone was a "major strength of the current study."

45. But when the results of the study were published in JAMA, the incidences of major and minor gastrointestinal complications were combined. Why the change? The results of the study as originally designed failed to show that the people who took Celebrex® developed significantly fewer major gastrointestinal complications than the people who took ibuprofen or diclofenac, even for just the first six months. Only by combining the minor GI symptoms with the more serious gastrointestinal complications could the article conclude that Celebrex® caused a statistically significant decrease in gastrointestinal complications compared with the other NSAIDs. As noted above, when the FDA looked at the results of the CLASS study in terms of the research question that had *originally* been posed, Celebrex® was not significantly safer than the other NSAIDs.

46. Finally, the most important measure of safety is the overall frequency of serious side effects – including but not limited to gastrointestinal side effects. For the full 12 months of the study, the people in the CLASS study who took Celebrex® experienced 11 percent more serious complications (in all body systems combined) than the people who took the older and less expensive anti-inflammatory drugs. This difference did not reach statistical significance but certainly is significant in countering Pharmacia's claim that Celebrex® is better than older NSAIDs because it's safer.

47. These findings contributed to the FDA's decision to send one of its rare Warning Letters to the CEO of Pharmacia in February 2001. The letter cites repeated unsubstantiated marketing claims that Celebrex® is the preferred NSAID for people

taking a blood thinner and that it is safe and effective for the treatment of acute pain – a use for which it is not approved – and points out that Pharmacia's marketing material fails to warn of the possibility of serious GI complications caused by the drug. The Warning Letter concludes by saying: Your promotional activities described above raise significant health and safety concerns in that they minimize crucial risk information and promote Celebrex® for unapproved new uses. In two previous untitled letters dated October 6, 1999, and April 6, 2000, we objected to your dissemination of promotional materials for Celebrex® that … contained unsubstantiated comparative claims, and lacked fair balance. Based upon your written assurances that this violative promotion of Celebrex® had been stopped, we considered these matters closed. Despite our prior written notification, and notwithstanding your assurances, Pharmacia has continued to engage in false or misleading promotion of Celebrex®.

48. Also included in the Warning Letter was the requirement that Pharmacia send out the "Dear Healthcare Provider" letter that had landed on my desk. Of course, the letter sent out by the manufacturer was not quite as specific as the FDA's Warning Letter. Few doctors, even if they had bothered to wade through the difficult language, had the time or inclination to find out the story behind the letter. As a result, ***doctors continued to prescribe Celebrex® for their patients based on the scientific evidence published in JAMA***. It was incomplete and presented an inaccurate picture of the so-called safety advantage of Celebrex® over other less expensive NSAIDs.

C. Marketing and Promotion

49. Thus, rather than financing studies to quantify the cardiovascular risks posed by Celebrex®, Defendants continued pouring money into advertising campaigns

that uniformly emphasized the gastrointestinal safety of Celebrex® while avoiding any mention of cardiovascular risks. Defendants pursued this strategy to benefit from the assumption that, in the absence of information to the contrary, Celebrex® possessed the same cardioprotective properties as traditional NSAIDs.

50. Defendants' advertising expenditures quickly reached historic levels. Pharmacia and Monsanto spent more than $78 million on consumer advertising for Celebrex® in the year 2000. Defendants spent more than $400 million on direct-to-consumer advertising for Celebrex® from 1999 to 2003.

51. In addition, Defendants' sales forces have blitzed doctors' offices with literature and verbal presentations designed to convince both doctors and consumers that Celebrex® was a superior drug for treatment of osteoarthritis, acute pain in adults, painful menstrual cycles and other types of disease. They have aggressively promoted Celebrex® as an improvement over other NSAIDs, like naproxen and ibuprofen, because it had a lower risk of side effects such as gastrointestinal ulcers and bleeding. Defendants did not promote or provide any balanced presentation as to Celebrex® as having an unacceptably high risk of other side effects, such as heart attack and stroke.

52. Such marketing efforts to physicians have become commonplace in recent years. Drugs, including Celebrex®, that might once have been used primarily by specialists are routinely promoted to, and prescribed by, doctors who are less familiar with the drugs' full research record. Drug companies, with Pfizer in the forefront, spent $8 billion on such "detailing" to physicians – i.e., sales people dropping by to leave marketing materials and speaking to physicians about their companies' drugs – in the 12 months through October 2004.

53. Such large-scale marketing efforts have paid huge dividends to Defendants and other drug companies. The number of blockbuster drugs, defined as drugs with more that $1 billion in annual retail prescription sales, was only 15 in 1999 but grew to 34 in 2003.

54. As a result of Defendants' uniformly misleading advertising campaigns, Celebrex® was wildly successful. Celebrex® became Pharmacia's best selling drug with more than $2.6 billion in sales for 2000 and $3.1 billion in sales for 2001. After acquiring Pharmacia, Pfizer has continued to enjoy blockbuster sales of Celebrex®, with $2.3 billion in revenue through the first three quarters of 2004.

D. Risks Posed by Celebrex®

55. Despite the effectiveness of their advertising campaigns, Defendants uniform failure to disclose the risk of cardiovascular injury from Celebrex® did not quell concerns about selective COX-2 inhibitors in the medical community.

56. In 1997, the link between COX-2 inhibition, prostacyclin levels and blood clotting was receiving sporadic attention in medical journals.

57. In 1998, independent doctors established a link between selective COX-2 inhibitors and increased blood clotting, and suggested that these drugs would cause an increase in clot-related cardiovascular events. These doctors suggested that these drugs should not be given to patients with known cardiovascular disease, and that patients taking these drugs would have to be monitored for cardiovascular complications.

58. In light of the blockbuster sales of Celebrex® and the related increase in serious cardiovascular events among patients taking such drugs, the link between selective COX-2 inhibition and cardiovascular problems received increased attention.

59. The cardiovascular safety of Celebrex® was directly challenged for the first time in August 2001, when independent doctors from the Cleveland Clinic published a metaanalysis of the CLASS trial that concluded these drugs posed an increased risk of adverse cardiovascular events compared to naproxen, a traditional NSAID. These doctors, specifically concerned with the increased number of heart attacks experienced by patients taking selective COX-2 inhibitors, urged Defendants to conduct trials to assess the cardiovascular risks of Celebrex®.

60. Over the next eight months, many pre-eminent doctors and medical organizations continued to discuss the cardiovascular risk of Celebrex®. The vast majority, regardless of whether they were on Defendants' payrolls, agreed that cardiovascular risk factors should be considered in deciding whether to prescribe Celebrex®, and that well designed, comprehensive studies were needed to assess the effects of selective COX-2 inhibitors on human heart function.

61. Despite the mounting evidence that Celebrex® cause or exacerbate clot-related cardiovascular disorders, Defendants have continued to issue uniformly misleading advertisements and promotional materials that tout Celebrex® as being safe and more effective than traditional NSAIDs for all patients without regard for cardiovascular risks.

62. The FDA has issued repeated warnings identifying these marketing statements as deceptive and illegal.

63. In October 1999, the FDA sent a warning letter to Searle identifying promotional materials for Celebrex® that violated the Federal Food, Drug and Cosmetic Act because they contained unsubstantiated comparative claims of superiority with regard to other NSAIDs, misrepresented the safety profile of Celebrex® and lacked fair balance with respect to the risks of taking Celebrex®.

64. In April 2000, the FDA sent a warning letter to Searle identifying promotional materials for Celebrex® that violated the Federal Food, Drug and Cosmetic Act because they misrepresented the safety profile of Celebrex®, contained unsubstantiated comparative claims of superiority with regard to other NSAIDs, and failed to provide any risk information concerning the use of Celebrex®.

65. In November 2000, the FDA sent a warning letter to Searle identifying promotional materials for Celebrex® that violated the Federal Food, Drug and Cosmetic Act because they suggested that Celebrex® is more effective than has been demonstrated by substantial evidence.

66. In February 2001, the FDA sent a warning letter to Pharmacia identifying promotional activities and materials for Celebrex® that violated the Federal Food, Drug and Cosmetic Act because they minimize the contraindications and risks associated with Celebrex® use and contained unsubstantiated comparative claims of superiority with regard to other NSAIDs.

67. Despite knowing the cardiovascular risks associated with Celebrex®, and having received numerous warnings from the FDA for downplaying risks associated with these drugs, Defendants sent “Dear Doctor” letters to thousands of

physicians nationwide in August 2001 "strongly support[ing] the cardiovascular safety profile" of Celebrex®.

68. Despite knowing the cardiovascular risks associated with Celebrex® and having received numerous warnings from the FDA for downplaying risks associated with these drugs, Defendants also sent "Dear Patient" letters from a prescription database of thousands of consumers in August 2001 that minimized the risk of "safety issues, specifically heart attacks and strokes" associated with Celebrex® while emphasizing that these drugs were "innovative, effective and safe" treatment options for osteoarthritis, without any mention of cardiovascular risks.

E. Misleading Promotion and Advertising

69. Defendants have spent hundreds of millions of dollars advertising Celebrex® directly to consumers. Celebrex® advertising and packaging materials do not contain any cardiovascular warnings or precautions. The only mentions of cardiovascular events are located in the "adverse reaction" (0.1%-1.9%) and "other serious adverse reaction" (<0.1%) sections, and do no more than list general cardiovascular problems experienced by participants in "12 controlled studies" involving Celebrex®.

70. Celebrex® advertising and packaging materials uniformly omit to disclose the following material facts: that there is a relationship between COX-2 inhibition and blood clotting; that Celebrex® poses a known risk of cardiovascular harm, not only to patients with heart disease and/or cardiovascular risk factors, but to all consumers; and that no clinical studies have been performed to test the safety of Celebrex® for patients with cardiovascular risk factors.

71. Defendants' advertising and packaging materials for Celebrex® are uniformly fraudulent and misleading, because they fail to warn consumers that Celebrex® poses known risks of blood clots, heart attack, stroke, unstable angina, cardiac clotting and hypertension for all people who ingest them; and cannot safely be ingested by patients with known heart disease or cardiovascular risk factors.

72. As an example, 1999 print advertisements ask: "What will you do on the day you discover Celebrex®?" The advertisements then state: "Discover what millions have turned to for arthritis pain relief." The advertisements claim that Celebrex® was a "scientific breakthrough: the first product to target only the COX-2 enzyme." They failed to explain, however, that Celebrex® is more expensive that other NSAIDs and is no more effective than those drugs. Those advertisements also state: "Celebrex® has been extensively studied in large clinical trials. The most common side effects were indigestion, diarrhea and abdominal pain. The percentage of patients who stopped taking Celebrex® due to all side effects (7.1%) was similar to sugar pill (6.1%)." The advertisements did not provide any information about potential adverse effects on consumers' hearts. Instead, at the end of a separate page in very small print, the advertisements state that the following adverse events, among others, occurred in 0.1-1.9% of patients regardless of causality: "***Cardiovascular***: Aggravated hypertension, angina pectoris, coronary artery disease, myocardial infarction." The advertisements then state, again in very small print: "Other serious adverse reactions which occur rarely (<0.1%), regardless of causality: The following serious adverse events have occurred rarely in patients, taking CELEBREX®. ***Cardiovascular***. Syncope,

congestive heart failure, ventricular fibrillation, pulmonary embolism, cerebrovascular accident, peripheral gangrene, thrombophlebitis…."

73. As another example, 2001 print advertisements state: "TRUSTED SAFETY – No dose-related increase in hypertension or peripheral edema." Instead, at the end of a separate page in very small print, the advertisements state that the following adverse events, among others, occurred in 0.1-1.9% of patients regardless of causality: "***Cardiovascular***: Aggravated hypertension, angina pectoris, coronary artery disease, myocardial infarction." The advertisements then state, again in very small print: "Other serious adverse reactions which occur rarely (<0.1%), regardless of causality: The following serious adverse events have occurred rarely in patients, taking CELEBREX®. Cases reported only in the postmarketing experience are indicated in italics. ***Cardiovascular***. Syncope, congestive heart failure, ventricular fibrillation, pulmonary embolism, cerebrovascular accident, peripheral gangrene, thrombophlebitis, *vasculitis*…."

74. Defendants again failed to inform consumers of the risks of heart problems in print advertisements for the year 2003. For example, one such advertisement shows a father and son, and states: "Lasting strength. Lasting relationships." The advertisement does not reveal any risk of heart problems, although it refers to other potential risks. In very small print on a separate page, however, the advertisement sets forth the same cardiovascular risks that the 2001 advertisements set forth.

FIRST CAUSE OF ACTION

STRICT LIABILITY – FAILURE TO WARN

75. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

76. The drug product previously described was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution, in that, and not by way of limitation, said product and its warnings, instructions and directions failed to warn of the dangerous propensities of said product, which risks were known or reasonably scientifically knowable to Defendants. The Defendants knew or should have known of the defective condition, characteristics and risks associated with said product, as previously set forth herein.

77. At all times herein mentioned, the aforementioned product was defective, and Defendants knew that the product was to be used by the user without inspection for defects therein. Moreover, Plaintiff Edward Finck neither knew, nor had reason to know at the time of the use of the subject products, of the existence of the aforementioned defects.

78. As a result of the defective condition of the aforementioned product, Plaintiff suffered injuries and damages as alleged herein.

SECOND CAUSE OF ACTION

NEGLIGENCE

79. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

80. At all times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Celebrex®.

81. At all times herein mentioned, Defendants negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold the aforementioned products and failed to adequately test and warn of the risks and dangers of the aforementioned products.

82. Despite the fact that Defendants knew or should have known that Celebrex® caused unreasonable, dangerous side effects, Defendants continued to market Celebrex® to consumers including Plaintiff Edward Finck, when there were safer alternative methods of treating osteoarthritis and acute pain.

83. Defendants knew or should have known that consumers such as Plaintiff Edward Finck would foreseeably suffer injury as result of Defendants' failure to exercise ordinary care as described above. Defendants' negligence was a proximate cause of Plaintiff's injuries, harm and the economic loss that Plaintiff suffered, and will continue to suffer, as described and prayed for herein.

THIRD CAUSE OF ACTION

FOR BREACH OF IMPLIED WARRANTY

84. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

85. Prior to the time that Plaintiff Edward Finck used the aforementioned product, Defendants impliedly warranted to him and his agents and physicians that said product was of merchantable quality and safe and fit for the use for which it was intended.

86. Plaintiff was and is unskilled in the research, design and manufacture of the aforementioned products and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using the aforementioned products.

87. The aforementioned product was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that Celebrex® had dangerous propensities when put to its intended use and would cause severe injuries to the user.

88. As a result of the aforementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION

FOR BREACH OF EXPRESS WARRANTY

89. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

90. At all times herein mentioned, Defendants expressly represented and warranted to Plaintiff Edward Finck and his agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned product was safe, effective, fit and proper for their intended use. In reliance upon said warranties, Plaintiff Edward Finck purchased said product.

91. In utilizing the aforementioned products, Plaintiff Edward Finck relied on the skill, judgment, representations and foregoing express warranties of the Defendants. Said warranties and representations were false in that the aforementioned products were not safe and were unfit for the uses for which they were intended.

92. As a result of the foregoing breach of express warranties by the Defendants, Plaintiff sustained the injuries and damages as herein alleged.

FIFTH CAUSE OF ACTION

DECEIT BY CONCEALMENT

93. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

94. Defendants, from the time that Celebrex® was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, willfully deceived Plaintiff Edward Finck by concealing from him, his physicians and the general public, the true facts concerning said pharmaceutical products, which the Defendants, had a duty to disclose.

95. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of the aforementioned drug products and willfully deceive Plaintiff Edward Finck, his physicians and the general public as to the health risks and consequences of the use of Celebrex®. Defendants were aware of the foregoing, and that Celebrex® was not safe, fit and effective for human consumption, the use of Celebrex® is hazardous to health, and Celebrex® has a

serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff as delineated herein.

96. The Defendants intentionally concealed and suppressed the true facts concerning Celebrex® with the intent to defraud Plaintiff Edward Finck, in that the Defendants knew that Plaintiff Edward Finck's physicians would not prescribe Celebrex®, and he would not have used Celebrex®, if they were aware of the true facts concerning the dangers of Celebrex®.

97. As a result of the foregoing fraudulent and deceitful conduct by the Defendants, Plaintiff suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

98. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

99. Defendants, from the time that Celebrex® was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, made false misrepresentations, as previously set forth herein, to plaintiff Edward Finck, his physicians and the general public, including but not limited to the misrepresentation that Celebrex® was safe, fit and effective for human consumption. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Celebrex® and willfully deceive Plaintiff Edward Finck, his physicians and the general public as to the health risks and consequences of the use of the aforementioned products.

100. The Defendants made the foregoing representations without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of said Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject products.

101. The foregoing representations by the Defendants were in fact false, in that Celebrex® was not safe, fit and effective for human consumption, the use of Celebrex® is hazardous to health, and Celebrex® has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff as delineated herein.

102. The foregoing representations by Defendants were made with the intention of inducing reliance and the prescription, purchase and use of Celebrex®.

103. In reliance on the misrepresentations by the Defendants, Plaintiff Edward Finck was induced to purchase and use Celebrex®. If Plaintiff Edward Finck had known of the true facts and the facts concealed by the Defendants, he would not have used Celebrex®. The reliance of Plaintiff Edward Finck upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

104. As a result of the foregoing negligent misrepresentations by the Defendants, Plaintiff suffered injuries and damages as alleged herein.

PUNITIVE DAMAGES ALLEGATIONS

(As to only the First, Second, Fifth, and Sixth Causes of Action)

105. Plaintiff incorporate by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

106. The acts, conduct, and omissions of Defendants as alleged throughout this Complaint were willful and malicious and were done with a conscious disregard for the rights of Plaintiff Edward Finck and other users of the Defendants' product and for the primary purpose of increasing defendants' profits from the sale and distribution of Celebrex®. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

107. Prior to the manufacturing, sale and distribution of said prescribed medication, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, had knowledge that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff Edward Finck and as such, said consumers of said drugs were unreasonably subjected to risk of injury or death from the consumption of said product.

108. Despite such knowledge, Defendants acting through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in said medication and

failed to warn the public, including Plaintiff Edward Finck, of the extreme risk of injury occasioned by said defects inherent in said medication. Defendants and their individual agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of said medication knowing persons would be exposed to serious danger in order to advance Defendants' own pecuniary interest and monetary profits.

109. Defendants' conduct was despicable, and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff Edward Finck, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiff prays for judgment against the Defendants as follows, as appropriate to each cause of action alleged:

1. General damages in an amount that will conform to proof at time of trial;

2. Special damages in an amount within the jurisdiction of the this Court and according to proof at the time of trial;

3. Loss of earnings and impaired earning capacity according to proof at the time of trial;

4. Future Medical expenses, according to proof at the time of trial;

5. For past and future mental and emotional distress, according to proof;

6. For punitive or exemplary damages according to proof on the First, Second, Fifth, and Sixth causes of action;

7. Restitution, disgorgement of profits, and other equitable relief;

8. Injunctive relief;

9. Attorney's fees;

10. For costs of suit incurred herein;

11. For pre-judgment interest as provided by law; and

12. For such other and further relief as the Court may deem just and proper.

RESPECTFULLY SUBMITTED this 15th day of December, 2006.

BEGAM, LEWIS & MARKS, P. A.

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ORIGINAL of the foregoing electronically filed this 15th day of December, 2006, with:

Clerk of the Court for the
United States District Court
for the District of Arizona

By: s/Deanna Allen